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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,258	12/12/2003	Giorgio Soldani	023349-00285	8654

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EXAMINER	
YAO, SAMCHUAN CUA	
ART UNIT	**PAPER NUMBER**
1733	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/733,258	SOLDANI, GIORGIO	
	Examiner	Art Unit	
	Sam Chuan C. Yao	1733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-25* is/are pending in the application.

4a) Of the above claim(s) *16-21* is/are withdrawn from consideration.

5)☒ Claim(s) *25* is/are allowed.

6)☒ Claim(s) *1,2,5-10,12-15,23 and 24* is/are rejected.

7)☒ Claim(s) *11 and 22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-2, 5-6, 9-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soldani (US 5,387,621) in view of Cline et al (US 6,161,723).

With respect to claims 1, 6, 9-10 and 12, Soldani discloses a system for making a tubular porous membrane, which is suitable for medical applications such as vascular prostheses, the system comprises:

a) a polymer solution including a natural or synthetic polymer and solvent, and a non-solvent for the polymer, the non-solvent including a water containing substance such as an alkanol;

b) an apparatus including

i) a rotating supporting mandrel;

ii) a bi-directionally moving carriage disposed adjacent to the mandrel moving in parallel relative to the mandrel, and further wherein a pair of spray guns are mounted therein to separately but simultaneously spray the polymer solution and the non-solvent onto the rotating mandrel;

iii) a mixing chamber (i.e. mixing means) for each spray gun (col. 2 lines 25-40; col. 3 lines 1-19; col. 4 lines 41-64; col. 5 line 41 to col. 6 line 36).

As for a limitation requiring 1st and 2nd mixing means for "... mixing together the components which form the fluid substances, in the desired relative mixing quantities, these relative quantities providing the membrane with given chemico-physical properties", at the outset, this limitation does not positively state whether the components are gaseous, liquid or solid and whether they are reactive to each other when mixed together. In fact, the presently recited claims do not even require a porous membrane to be positively derived from (i.e. made of) the recited components. While not explicitly stated in Soldani, the nitrogen gas and an unstable polymer solution or a nonsolvent (precipitating fluid) must be mixed at a predetermined "relative quantity" in a "mixing chamber" (emphasis added; col. 6 lines 17-22). For instance, if relative amount (for instance) in volume between a nitrogen gas and a polymer solution/nonsolvent is (say) 100,000/1 or vice versa, then it would be difficult, if not possible, to form a porous gel-like membrane having a desired "chemico-physical properties", because a desired spraying characteristic would not be achieved if a proper relative amount is not obtained. See for instance the teachings of the Cline et al patent, where it teaches incorporating a pressurized gas to a dispensing solution in a sprayer to obtain an appropriate spraying characteristic (col. 16 lines figure 27). Equally important, the presently recited claims are directed to an apparatus. It is stated in MPEP 2115 that "Inclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." In re Young, 25 USPQ 69 (CCPA 1935) (as restated in In re Otto, 136 USPQ 458, 459 (CCPA 1963).

Additionally, MPEP 2114 further states: "Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function.". In re Danley, 120 USPQ 528, 531 (CCPA 1959) and "Apparatus claims cover what the device is, not what a device does" (emphasis in original) Hewlett-Packard Co. v. Bausch & Lomb Inc., 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Moreover, "A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all structural limitations of the claim." Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). In the present case, a gas supply tank taught by Soldani is taken to be capable of handling a component in the presently claimed apparatus. For these reasons, the mixing means limitation fails to define over a mixing chamber taught by Soldani. As for using at least two mixing means, Soldani teaches using two spray means. This would have reasonably suggested that two mixing means are used in an apparatus of Soldanii.

As for a limitation of using a pump downstream from a mixing means and upstream from a nozzle, it would have been obvious in the art to provide a pump for supplying the solutions to the sprayers in an apparatus of Soldani as such is an art recognized way for supplying a fluid to a spraying means at a desired fluid pressure as exemplified in the teachings of Cline et al (col. 5 line 4 to col. 6 line 6; figure 1). In order to effectively deliver fluid materials from a mixer to a nozzle

at a desired fluid pressure, it would have been an obvious expediency in the art to provide a pump between the mixer and the nozzle.

As for a limitation of reserves being connected to a spray means, such is taken to naturally flow from an apparatus of Soldani. See for instance column 6 lines 17-23. Stored components in its respective reservoir in Soldani must be connected to a spray means via a conduit and a mixing means.

With respect to claim 2, Soldani teaches that "the degree of porosity of membrane can be varied by adding different amount of nonsolvents or by using nonsolvents of differing chemical compositions to the polymeric solution." (col. 3 lines 25-35; col. 4 lines 24-30). Additionally and more important, Soldani discloses suitable ranges of concentration for the polymer solution and the nonsolvent (Table 1). It would have been obvious in the art to provide a controller to the mixing means in Soldani as such is an art recognized effective and convenient way for automatically varying the concentration in a solution to a desired preset concentration by controlling the amount of feed components to be added into a mixing means.

With respect to claim 5, a preference on whether to provide a single or multiple pressurized nitrogen gas tanks is taken to be well within the purview of choice in the art. A component recited in claim 1 corresponds to a 1st nitrogen gas from a 1st gas tank (or the 1st tank is capable of handling the recited component), while the pressurized gas recited in this claim corresponds to a 2nd nitrogen gas from a 2nd gas tank.

3. Claims 7-8 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references set forth in numbered paragraph 2 as applied to claim 1 or 2 above, and further in view of Chouinard (US 6,709,455) for reasons of record set forth in a prior office action dated 10-05-06 numbered paragraph 6 and for reason set forth hereinafter.

With respect to claim 8, see column 9 lines 44-48 of the Chouinard patent, where it discloses a sprayed SGM on a mandrel is heated in an oven (i.e. heating element) for a desired period of time. Since the oven is capable of heating "a given zone (48) close to the stent", the limitation in this claim fails to define over the oven heater taught by Chouinard. In any event, a preference on whether to use an oven or a heating element disposed close to a stent (so that it heat a zone close to the stent) is taken to be well within the purview of choice in the art. None, but only the expected result would have been achieved.

4. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Soldani (US 5,387,621) in view of Smith (US 3,926,103).

The discussion of the Soldari patent set forth in numbered paragraph 2 is incorporated herein.

As for a limitation that a mixing means is disposed upstream from a spraying means, as has been noted in a prior office action, though not explicitly disclosed, the mixing chambers must inherently be disposed upstream from the spray-guns in order to supply a polymer solution and a non-solvent to the spray guns by flowing them from the source through a conduit to the spray guns. In any event,

such would have been obvious in the art as such is an art recognized effective way for providing a fluid mixture and delivering it to a spray means.

As for an added limitation of "an extractor hood positioned in front of the nozzles", Soldani teaches using a "chemical fume hood" (col. 6 lines 23-36). Moreover, Smith teaches disposing an exhaust hood (30) in front of a spraying means to effectively capture chemical fumes (col. 1 line 7 to col. 2 line 68; figure 1). It would have been obvious in the art to incorporate an extractor hood in an apparatus of Soldani where it is disposed in front of a spraying means in order to effectively capture unwanted fumes.

5. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references set forth in numbered paragraph 4 as applied to claim 23 above, and further in view of Cline et al (US 6,161,723).

It would have been obvious in the art to provide a pump for supplying the solutions to the sprayers in a system of Soldani as such is an art recognized way for supplying a fluid to a spraying means at a desired fluid pressure as exemplified in the teachings of Cline et al (col. 5 line 4 to col. 6 line 6; figure 1) thereby obtaining a desired flow characteristic to a spray system of Soldani. As for a location of the recited pump, it would have been an obvious expediency in the art to provide a pump between the mixer and the nozzle in order to deliver effectively fluid materials from a mixer to a nozzle at a desired fluid pressure.

Allowable Subject Matter

6. Claims 11 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Claim 25 is allowed.

Response to Arguments

8. Applicant's arguments filed on 02-02-07 have been fully considered but they are not persuasive.

On page 12 full paragraph 1, Counsel argued that "A [mixing] chamber connected to a glass reservoir for an unstable polymer solution **or** a non-solvent and to a compressed nitrogen tank is provided for each nozzle." (word inserted; and bold-face and emphasis in original). Examiner agrees. However, as has been noted above, this limitation does not positively state whether the components are gaseous, liquid or solid and whether they are reactive to each other when mixed together. In fact, the presently recited claims do not even require a porous membrane to be positively derived from (i.e. made of) the recited components. While it is not explicitly stated in Soldani, the nitrogen gas and an unstable polymer solution or a nonsolvent (precipitating fluid) must be mixed at a predetermined "relative quantity". For instance, if relative amount (for instance) in volume between a nitrogen gas and a polymer solution/nonsolvent is (say) 100,000/1 or vice versa, then it would be difficult, if not possible, to form a porous gel-like membrane having a desired "chemico-physical properties",

because a desired spraying characteristic would not be achievable if a proper relative quantity is not obtained. See for instance the teachings of the Cline et al patent, where it teaches incorporating a pressurized gas to a dispensing solution in a sprayer to obtain an appropriate spraying characteristic (col. 16 lines figure 27). Equally important, the presently recited claims are directed to an apparatus. It is stated in MPEP 2115 that, "Inclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." In re Young, 25 USPQ 69 (CCPA 1935) (as restated in In re Otto, 136 USPQ 458, 459 (CCPA 1963). Additionally, MPEP 2114 further states: "Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function.". In re Danley, 120 USPQ 528, 531 (CCPA 1959) and "Apparatus claims cover what the device is, not what a device does" (emphasis in original) Hewlett-Packard Co. v. Bausch & Lomb Inc., 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). Moreover, "A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all structural limitations of the claim." Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). In the present case, a gas supply tank taught by Soldani is taken to be capable of handling a component in the presently claimed apparatus. For these reasons, the mixing means limitation in the claims fails to define over the mixer taught by Soldani.

As for Counsel's arguments regarding the application and location of two pumps, such would have been obvious in the art for reasons set forth above.

On page 12 full paragraph 3, Counsel argued that, "Nitrogen is not a component of the porous membrane but is a pressurizing gas ...". Examiner agrees. However, as has been noted earlier, neither does the presently claimed invention. In other words, the claims as presently recited do not require positively a porous membrane to be composed of the recited components. The claims merely require "... starting with fluid substances consisting of mixture of two or more components" and these substances are sprayed onto a support to form a membrane. Likewise, a substance in a mixing chamber is composed of a polymer solution or nonsolvent, and pressurized nitrogen, and this substance is sprayed onto a support to form a porous membrane. Equally important and in any event, the presently recited claims are directed to an apparatus. As has been noted above, "Apparatus claims cover what the device is, not what a device does". In the present case, the presently claimed mixing means fails to define a mixing chamber of Soldani, because a gas tank in Soldani is reasonably taken to be capable of handling a component in the claimed apparatus. Counsel further argued that, "a "mixing chamber" is not a mixing means within the meaning of the patent application ...". Examiner strongly disagrees. After a cursory review of Applicant's specification, Examiner did not find any special meaning or definition on this term. It is quite clear that the mixing chamber in Soldani is certainly capable of mixing applicant's components.

On page 13, Counsel argued that, "... the components [in Soldani] are mixed ... outside the machine so as to obtain a mixture ("polymer solution") which is, thereafter, placed in the glass reservoir" (words inserted; quotation in original). It is respectfully submitted that, Counsel's argument is off point. The presently recited claims are not directed to a process, but rather, as has been repeatedly noted above, are directed to an apparatus. The glass reservoir is clearly capable of handling a component recited in the claims. Equally important, one of the components recited in the apparatus claims is taken to embrace a polymer solution in Soldani.

As for Counsel's argument on page 13 regarding "a hood being positioned in front of the nozzles" (emphasis added), such would have been obvious in the art for reasons set forth in numbered paragraph 4.

On page 14 full paragraph 2, Counsel strenuously traverses a holding by Examiner that an oven taught by Chouinard in combination with an apparatus of Soldani meet the limitation in claim 8. At the outset, this claim does not positively require disposing a heating element close to a stent, but rather it merely requires the heating element is "designed to heat a given zone close to the stent". Additionally, this claim does not also require positively heating ONLY "a given zone close to the stent". Since heat is applied throughout a chamber of an oven, then an oven must naturally be designed to heat a given zone close to a stent. In any event, it would have been well within the purview of choice in the art to

choose from among well known heating devices in an apparatus of Soldani for a production of a stent.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sam Chuan C. Yao whose telephone number is (571) 272-1224. The examiner can normally be reached on Monday-Friday with second Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Richard Crispino can be reached on (571) 272-1171. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sam Chuan C. Yao
Primary Examiner
Art Unit 1733

Scy
03-16-07